

REMARKS

In the present Office Action, claims 1 through 6 were examined. Claims 1 through 6 were rejected, no claims were objected to, and no claims were allowed.

By this Amendment, claims 1 and 5 have been amended, claims 2 and 14 have been canceled, and no claims have been added. Accordingly, claims 1, 3, 5 and 6 are presented for further examination. No new matter has been added. By this Amendment, claims 1, 3, 5 and 6 are believed to be in condition for allowance.

Rejections under 35 USC §102

The Examiner rejected claims 1 through 6 under 35 U.S.C. §102(b) as being anticipated by Wolf (U.S. Patent No. 5,809,997). Applicant respectfully traverses this rejection for the following reasons.

Firstly, Wolf relates to an electronic chronolog device which can be attached to a multidose inhaler (MDI). Such MDIs are very commonplace, requiring the canister to be depressed within the casing in order to deliver a metered dose of whatever drug is contained within the canister in the form of a spray. The patient must time the depression of the canister with the commencement of inhalation through the device. The delivery of the drug depends on a number of factors, such as correctly timing of the release of the drug in relation to the commencement of inhalation by the patient, the speed of the inhalation breath, and the duration of the inhalation breath. The chronolog includes an arm which is moved by the depression of the canister, and a thermistor which is arranged to detect and measure inhalation.

One of the aims of Wolf is described in column 3 lines 45 to 49 of the reference where it is stated that it is to be used to more properly control the behavior with which a patient uses the MDI. Thus, the chronolog can be used to effectively train a patient in the use of the MDI. If the patient is not timing the release of the drug appropriately, then this will be indicated to the patient. If the patient inhales too fast, or too slowly, then this will be indicated to the patient. Also, if the patient does not hold his breath for a long enough period of time, then this will also be indicated so that the patient can learn from the chronolog.

In addition, these results can be recorded by the chronolog. However, it is clear that what is being recorded is whether or not each drug delivery falls within the limits set

by the manufacturer of the device. For example, where a patient uses the device correctly, a pass will be recorded. The peak flow will not, for example, be recorded, and nor will the time difference between commencing inhalation and releasing the drug. The chronolog is merely recording the pass or fail of each treatment. For an MDI, this may be adequate information.

In addition, it should be appreciated that an MDI is a “one shot” device. That is, it delivers the drug into a single inhalation of a patient. Thus, the patient is not exhibiting a normal breathing maneuver during treatment with an MDI, but is carrying out a special single inhalation to conform with the MDI. That is, at the commencement of inhalation, the drug is released, and the patient continues to inhale to a specified inhalation rate, and then holds their breath at the end of inhalation before exhaling. Such a maneuver is not a natural breathing pattern, but an artificial inhalation.

Contrary to this, the present invention, as defined in the amended claims, relates to a system in which the drug delivery device is arranged to deliver the drug to the patient over a plurality of breaths. Thus, the drug delivery device conforms to the patient’s breathing pattern, rather than the patient conforming to the drug delivery device. This means that a patient, during drug delivery can breath normally. They do not need to perform special breathing maneuvers. This is significant because the breath analyzer analyzes a patient’s breathing, and not just a patient’s inhalation. It is working on the basis of the full breathing pattern, including inhalation, exhalation, rest periods and periods of time in which the patient is not inhaling nor exhaling. This enables the patient’s breathing characteristics to be determined by the data analyzer. No such breathing characteristics can be derived during the use of an MDI because an unnatural inhalation maneuver is executed, not natural breathing.

Since natural breathing is analyzed, the invention further includes a trend generator which analyzes the breath information and the characteristics of the patient’s breathing over a number of drug deliveries. Thus, if a patient uses the drug delivery device once each day for a month, the trend generator is able to identify any changes in the condition of a patient over that month. For example, if during that month, the patient’s lung condition deteriorates, this will be identified by the minute volume being increased to compensate for poor lung ventilation. By trending the breath information and the patient’s breathing characteristics, it is possible for a clinician to intervene before respiratory failure

is experienced. In the Office Action, the Examiner indicates that a data analyzer including a trend generator and means for identifying non-compliant use of the drug delivery device is disclosed in column 6 lines 16-21.

However, Column 6 lines 16 to 21 of Wolf, refers to deviation from correct usage being detected. However, this not the identification of a trend from treatment to treatment, merely identifying non-compliant usage of the drug delivery device. Clearly, if a particular deviation from compliant use is exhibited regularly, this must be corrected, but this should not be considered to be a trend generator.

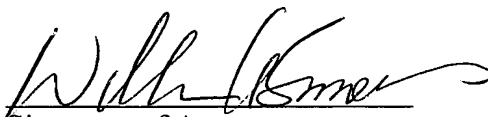
Accordingly, Applicant submits that this reference, anticipate or make obvious the invention as presently claimed and that the application is now in condition for allowance. Therefore, Applicant respectfully requests reconsideration and further examination of the application and the Examiner is respectfully requested to take such proper actions so that a patent will issue herefrom as soon as possible.

If the Examiner has any questions or believes that a discussion with Applicant's attorney would expedite prosecution, the Examiner is invited and encouraged to contact the undersigned at the telephone number below.

Please apply any credits or charge any deficiencies to our Deposit Account No. 23-1665.

Respectfully submitted,
JONATHAN STANLEY HAROLD DENYER, ET AL.

Date: August 29, 2003
Reg. No. 27,096


Signature of Attorney
William A. Simons
WIGGIN & DANA LLP
One Century Tower
New Haven, CT 06508-1832
Telephone: (203) 498-4502
Facsimile: (203) 782-2889